



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/801,443	03/07/2001	Suneel K. Gupta	ARC 2863-N1	7756

7590 06/26/2002
ALZA Corporation
1900 Charleston Road, M10-3
(P.O. Box 7210)
Mountain View, CA 94039-7210

EXAMINER

TRAN, SUSAN T

ART UNIT	PAPER NUMBER
----------	--------------

1615

DATE MAILED: 06/26/2002

6

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/801,443

Applicant(s)

Gupta et al.

Examiner

Susan Tran

Art Unit

1615



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Apr 5, 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

Art Unit: 1615

DETAILED ACTION

Receipt is acknowledged of applicants' Information Disclosure Statement filed 03/07/01, Extension of Time 04/05/02, Amendment A filed 04/05/02, and Power of Attorney filed 04/05/02.

Response to Arguments

1. Applicant's arguments filed 04/05/02 have been fully considered but they are not persuasive. The examiner maintains the original rejections:

Claims 1, 2, and 4 are rejected under 35 U.S.C. 102(b) as being anticipated by Baichwal US 5,399,359.

Applicant argues that while Baichwal may disclose a sustained release dosage form, applicant's invention is not anticipated since Baichwal does not teach dosage form to increase the therapeutic index of oxybutynin. Baichwal's dosage releases more than 50% of their active ingredient within the first hour, which reduces bioavailability of oxybutynin compared to applicant's invention disclosed in applicant's specification page 32. In response to applicant's argument, first, the rejection claims are composition claims, and therefor the patentability is based on the product itself, not the process of using it, nor the method of making it. Second, it is noted that the features upon which applicant relies (i.e., the release rate disclosed in page 32) are not recited in the rejected claims. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van*

Art Unit: 1615

Geuns, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Furthermore, Baichwal does recognize the bioavailability of the drug, as well as the therapeutic effect of blood level of the medicament for at least about 24 hours (column 2, lines 5-49). Accordingly, the desire of increasing the therapeutic index of oxybutynin is clearly inherent by the teachings of Baichwal.

Applicant argues that Baichwal's matrix dosage was significantly affected by meals, however, applicant's claimed invention was found to have sustained blood plasma concentrations unaffected by meals. However, the feature upon which applicant argues on has not been introduced in the rejected claims. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

2. Claims 7-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Aberg et al. US 5,532,278.

Applicant argues that claims 7-14 are not anticipated by Aberg because Aberg's invention is free of its R enantiomers, while applicant's invention does not require use of a specific enantiomer, but allows use of the racemic mixture. Contrary to the applicant's argument, the "comprising" language allows use of any enantiomer, any racemic mixture, including the (S)-oxybutynin taught by Aberg. The particular enantiomer of oxybutynin is not precluded by the "comprising" language.

Art Unit: 1615

Claims 3, 5, and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baichwal.

Applicant argues that there is no teaching in Baichwal to motivate a slower rate of release. Contrary to the applicant's argument, Baichwal at column 5, lines 45-48 teaches the use of release rate modifying ingredient, which is capable of slowing the release rate of the final product. Furthermore, Baichwal also recognizes the desire of having a sustained release dosage that provides a therapeutically effective blood level of the medicament for at least about 24 hours. Hence, it is the position of the examiner that claims 3, 5, and 6 are obvious over Baichwal.

6. Claims 7-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Aberg et al., in view of Baichwal.

Applicant argues that the examiner is improperly attempting to pick and choose in hindsight pieces of Aberg and Baichwal, which are not taught for the purpose asserted. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ

Art Unit: 1615

209 (CCPA 1971). Regarding to the suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, although Aberg teaches the composition can be administered by controlled release means, Aberg does not teach controlled release over 24 hours. Baichwal is relied upon solely for the teaching of a 24 hour dosage form containing oxybutynin.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however,

Art Unit: 1615


will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Tran whose telephone number is (703) 306-5816. The examiner can normally be reached on Monday through Thursday from 6:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.


THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600